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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,775	07/22/2003	Paulus Wohlfart	02481.1828-01000	6100
22852	7590	02/27/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			HENLEY III, RAYMOND J	
		ART UNIT		PAPER NUMBER
		1614		

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/623,775	WOHLFART ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 11-28 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. 10/073,330.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/21/2003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____                                     |

**CLAIMS 11-28 ARE PRESENTED FOR EXAMINATION**

Applicants' Preliminary Amendment and Information Disclosure Statement filed July 21, 2003 have been received and entered into the application. Accordingly, the specification at page 1 has been amended, claims 1-10 have been canceled and claims 11-28 have been added. Also, as reflected by the attached, completed copy of form PTO-1449 (2 pages), the cited references have been considered.

***Specification***

The abstract of the disclosure is objected to because it fails to be in the form of a single paragraph. Correction is required. See MPEP § 608.01(b) under the subheading "Language and Format".

Further, the specification is objected to because the status of parent application Ser. No. 10/073,330 is not updated to reflect its current status as U.S. Patent No. 6,617,359. Correction is required.

***Claim Rejection - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating the variety of diseases and/or conditions in a mammal suffering from such disease and/or disorder, does not reasonably provide enablement for a method of treating, in general, a patient who suffers from the above mentioned diseases and/or disorders where, as in the present claims, no specific therapeutic objective is set forth for

the actual treatment.

Insofar as no therapeutic objective to be achieved in the patients suffering from the diseases/disorders has been set forth in the claims, the purpose of "treating" is not limited and such reads the use of the claim designated ingredient as a panacea. The art currently is unaware of any single agent, or combination of agents that could be used for the treatment of any and all disease states. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

When the above factors as applied to the present application (see below) are weighed, it is the examiner's position that the present specification would only enable the skilled artisan to practice a method of treatment wherein the therapeutic objective of such treatment has ~~not~~ been set forth.

DA 2/25/04

(1) The nature of the invention.

The claims set forth merely a method of treating a host who is defined by the disorder from which he/she is suffering.

(2) The state of the prior art.

The art currently is unaware of any single agent, or combination of agents that could be used for the treatment of any and all disease states which is encompassed by the present claims.

(3) The relative skill of those in the art.

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art.

The unpredictability of the pharmaceutical chemistry/medical art is very high.

As an example of the unpredictability in the art, the Examiner points to two very well known therapeutic agents, namely quinine and quinidine. Quinine and quinidine differ from each other only in that they are mirror images of each other. However, the therapeutic activity of each is quite distinct. Namely, quinine is effective for reducing a fever or as an anesthetic, while quinidine finds application as a cardiac suppressant.

(5) The breadth of the claims.

The claims set forth merely a method of treating a host who is defined by the disorder he/she is suffering.

(6) The amount of direction or guidance presented.

There is adequate direction and guidance provided throughout the present specification that would enable the skilled artisan to practice a method of treating the variety of diseases/disorders in a mammal suffering therefrom. This, however, is not the scope of the claimed invention as it is directed to the broad objective of “treating a patient” who suffers from certain diseases/disorders.

(7) The presence or absence of working examples.

The present specification contains no working examples that would enable the skilled artisan to practice the invention of the scope presently claimed.

(8) The quantity of experimentation necessary.

Because of the fact that the art is currently unaware of a agent that is broadly useful for “treating a patient”, no amount of experimentation, undue or otherwise, could be employed by the skilled artisan to arrive at the claimed objective.

***Suggestion for Overcoming the Above Rejection***

In order to overcome the present rejection, applicants may wish to consider amending the independent claims to read in the following or a similar manner. As an example, the Examiner will use present claim 11 (in-part):

“11. A method for treating cardiovascular disease in a mammal suffering therefrom, which method comprises...”.

***Double Patenting***

Claims 11-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-27 of U.S. Patent No. 6,617,359 (Wohlfart et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because in the present claims, the diseases/disorders are merely divided differently among the several claim sets than in the patented claims.

Also, while the present claims are silent as to the action of the claimed compound, i.e., 4-fluoro-N-indan-2-yl benzamide, to stimulate the expression of endothelial NO-synthase in the host as in the patent claims, such would be an inherent feature of the present methods because in both the patented claims and the present claims the same host is being treated with the same active agent.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

Feb.25, 2004